

# **EXHIBIT 101**



Samson et al. v. Crittenden et al.

Patent Interference No. 101,634

Application of Wilfred J. Samson, Ronald G. Williams and Craig E. Mar, filed July 30, 1985, Serial No. 760,636.

Application of James F. Crittenden and James J. Frassica, filed May 2, 1985, Serial No. 729,541.

Board of Patent Appeals and Interferences

*1989 Pat. App. LEXIS 25; 14 U.S.P.Q.2D (BNA) 1810*

June 6, 1989, Final Hearing  
September 27, 1989, Decided

[\*1]

Before Boler, Caroff and Meister, Examiners-in-Chief.

**COUNSEL:**

Edward J. Lynch, David N. Makous, John S. Christopher, Vern Schooley and Richard A. Bardin for Samson et al.  
Oral argument by Edward J. Lynch.

David Wolf, George L. Greenfield, Stanley Sacks, Lawrence M. Green, Edward R. Schwartz, Louis Orenbuch, David M. Driscoll, Arthur Z. Bookstein, Edward F. Perlman, Alfred H. Rosen, John L. Welch, Paul Kudirka, Susan Haddad Hage, Therese A. Hendricks and Edward R. Gates for Crittenden et al. Oral argument by Arthur Z. Bookstein.

**OPINIONBY: BOLER**

**OPINION:**

Boler, Examiner-in-chief.

This interference involves an application of Samson et al (junior party), assigned to Advanced Cardiovascular Systems, Inc. (ACS), and an application of Crittenden et al (senior party), assigned to C. R. Bard, Inc. (Bard).

The subject matter in issue is defined by two counts which read as follows:

Count 1

In a dual dilatation catheter assembly for dilating a stenosis in a vessel, a first dilatation catheter, comprising a

tubular element having a main lumen extending therethrough, a second tubular lumen extending longitudinally within the tubular element and forming an inflation lumen, a balloon carried by the tubular element [\*2] at its distal end and having its interior in communication with the inflation lumen, a second dilatation catheter extending through the main lumen in the tubular element of the first dilatation catheter, a flexible elongate tubular element having a lumen extending therethrough, an inflatable balloon carried by the flexible tubular element of the second dilatation catheter and having its interior in communication with the lumen of the flexible tubular element of the second dilatation catheter, the balloon of the second dilatation catheter being elongate and having a diameter when inflated capable of dilating a stenosis, the balloon of the second dilatation catheter having a collapsed diameter which is less than the interior diameter of the lumen of the tubular element of the first dilatation catheter whereby the second dilatation catheter can be inserted and removed from the first dilatation catheter.

#### Count 2

In a method for dilating stenoses in blood vessels having very small openings therein utilizing a dual dilatation catheter assembly comprised of a first balloon dilatation catheter having a lumen extending therethrough and a second balloon dilatation catheter of a size which [\*3] is adapted to extend through the lumen in the first balloon dilatation catheter, introducing the first dilatation catheter into the vessel so that the distal extremity of the first balloon dilatation catheter is in the vicinity of the stenosis, introducing the second balloon dilatation catheter into the first balloon dilatation catheter so that the distal extremity extends beyond the distal extremity of the first balloon dilatation catheter, advancing the second balloon dilatation catheter through the stenosis so that the balloon of the second balloon dilatation catheter assembly is disposed in the stenosis, inflating the second balloon dilatation catheter to dilate the stenosis, removing the second dilatation catheter from the stenosis, advancing the first dilatation catheter through the stenosis so that the balloon of the first balloon dilatation catheter is positioned in the stenosis, inflating the balloon of the first balloon dilatation catheter, and removing the first balloon dilatation catheter from the stenosis, and removing the first and second balloon dilatation catheters from the vessel.

The claims of the parties which correspond to the respective counts are:

| Count | Samson et al | Crittenden et al |
|-------|--------------|------------------|
| 1     | 1-24 and 26  | 1-14 and 48      |
| 2     | 25           | 15-26 and 49     |

[\*4]

Both parties have submitted an evidentiary record under 37 CFR 1.653 and filed briefs for final hearing pursuant to 37 CFR 1.656.

#### I

#### SENIOR PARTY'S MOTION TO SUPPRESS

Crittenden et al have filed a motion to suppress certain of the junior party's exhibits (Paper No. 75). Samson et al have opposed the motion (Paper No. 77). In the motion, Crittenden et al request that junior party Exhibits JPX 8-13, JPX 19-21 and all documents in group exhibit JPX 4 except pages 00551, 00590 and 00612 be denied consideration because Samson et al did not comply with the requirements of 37 CFR 1.673(b)(1) in that they did not provide a list of the documents to be relied upon. Crittenden et al state "[A]lthough junior party copied senior party with a substantial number of documents a few days before the first deposition, there was never any notice by junior party as to which of those documents were going to be relied on in any particular deposition. As a result, senior party did not have adequate opportunity to prepare for each of the testimony depositions taken by junior party and was prejudiced." Crittenden et al further contend that these exhibits are inadmissible as hearsay to the extent [\*5] that they are offered to prove the truth of their contents, and that JPX 8-13 were offered as part of a mass offering of exhibits which precluded the senior party from effectively dealing with the exhibits in the context of the testimony in which they were originally identified.

Under the provisions of 37 CFR 1.673(b)(1), a party is required to serve a list and copy of each document in the party's possession, custody, or control upon which the party intends to rely at any deposition. In our view, the rule does not require a party to state which documents are going to be relied upon at any given deposition but only that the documents served may be relied upon at one or more of the scheduled depositions. Thus, Samson et al are not precluded from relying upon the documents merely because they did not state in which deposition or depositions each document would be relied upon.

The senior party has not established in this case that they were prejudiced in their cross-examination of the junior party witnesses by the failure of the junior party to serve a list of the documents. The junior party points out that 37 CFR 1.673(c) states that a party shall not be entitled to rely at any [\*6] deposition on a document not served as required by paragraph (b) of the section and says nothing about the list of the documents referred to in paragraph (b). Since there is no question that the documents under consideration were served, the junior party asserts that they were entitled to rely on them at the depositions which they took. Although the failure to serve a list of the documents along with the documents may under different circumstances be a ground for denying a party the right to rely on the documents served under 37 CFR 1.673(b)(1), we hold that under the facts of this case the failure to do so has not been shown to have prejudiced the senior party to the point where the junior party should be denied the right to rely on the documents under consideration.

To the extent that the senior party timely and properly objected to the exhibits on the ground of hearsay, the exhibits will be admitted merely to show that the statement was made and not for the truth of its contents. With respect to JPX 4, Williams was the author of all but three pages thereof and so testified at JPR 369. Of the three pages not authored by Williams, the senior party does not object to page 00590. [\*7] Thus, the only pages of JPX 4 properly subject to the stated objection are pages 00618 and 00620 authored by McGregor, who did not testify. Mar was the author of and testified with respect to JPX 8-13 at JPR 90 through 100 and thus these exhibits are not inadmissible on the ground of hearsay as alleged by the senior party. JPX 19-21 are patents in which witness Samson and/or Williams is a named inventor. Thus, these exhibits are not subject to the stated hearsay objection, in our view. Although these exhibits may not have been properly objected to on the ground of hearsay, the above documents and others of record identified only by Mar, Williams and/or Samson are entitled to no weight since they have not been authenticated as to date or content by evidence independent of the inventors. *Reese v. Hurst*, 661 F.2d 1222, 211 USPQ 936 (CCPA 1981).

A party is entitled to object to an exhibit when it is identified or at any time during the examination of the witness with respect thereto when a ground for objection becomes apparent. Thus, the fact that the junior party offered JPX 8-13 as part of a mass offering of exhibits is not deemed to be an adequate ground for denying their [\*8] admission into evidence.

The motion is denied except with respect to pages 00618 and 00620 of JPX 4, which are admitted merely to show that the statements therein were made.

## II

### JUNIOR PARTY'S CASE FOR PRIORITY

Since this interference involves copending applications, the burden on Samson et al, the junior party, is to prove their case by a preponderance of the evidence. *Morgan v. Hirsch*, 728 F.2d 1449, 221 USPQ 193, 194 (Fed. Cir. 1984).

The named inventors in the junior party's application are Wilfred J. Samson, Ronald G. Williams and Craig E. Mar. There are 26 claims in the junior party's application. As noted above, claims 1 through 24 and 26 correspond to count 1 and claim 25 corresponds to count 2. On page 3, inter alia, of the junior party's main brief, the junior party says that the invention of counts 1 and 2 was conceived by Wilfred J. Samson at least as early as June 17, 1983. The evidence presented clearly shows that neither Williams nor Mar became involved with the invention until the fall of 1984. However, the junior party has not filed a motion under 37 CFR 1.634 to correct the inventorship of their application.

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Their preliminary statement alleges [\*9] that the invention of counts 1 and 2 was made in the United States by Samson, Williams and Mar and no attempt has been made pursuant to 37 CFR 1.628 to correct the preliminary statement by alleging that Samson was the sole inventor of the invention in counts 1 and 2. Not only does the junior party's main brief allege that the invention was conceived by Samson alone in June 1973, the senior party on page 5 of their brief concede that it was. If Samson sole were the first inventor of the subject matter in issue, that subject matter would not be patentable to either party to this interference since Samson sole is not a party.

Where a party is willing to concede a date of conception by another involved party, we would ordinarily accept that date as proven. However, here the senior party has merely conceded that someone not a party to the interference conceived the invention in June 1983, that concession is deemed to be of no significance as to the conception date of Samson et al. In this regard, we note that Mar testified that he was not aware of and did not become involved in the project that resulted in the invention until late November 1984 (JPR 31, 36, 115). Thus, the party [\*10] Samson et al could not have been in possession of conception of the invention in counts 1 and 2 prior to late November 1984. In addition, since Williams and Mar are inventors, their testimony relating to conception and reduction to practice as well as Samson's must be corroborated by independent evidence. *Coleman v. Dines*, 754 F.2d 353, 224 USPQ 857, 862 (Fed. Cir. 1985); *Davis v. Reddy*, 620 F.2d 885, 205 USPQ 1065 (CCPA 1980); *Reese v. Hurst*, *supra*. The testimony of joint inventors does not establish independent corroboration. *Anderson v. Pieper*, 442 F.2d 982, 169 USPQ 788 (CCPA 1971); *Medtronic, Inc. v. Daig Corp.*, 221 USPQ 595, 604 (D.C. Minn. 1983).

A review of Samson's testimony shows that contrary to the assertions in the junior party's brief, he merely had an idea or desired result in mind in June 1983 of a structure for performing the function of the invention in counts 1 and 2 but did not have a conception thereof because he did not know how to make a catheter small enough in diameter to pass through the lumen of the Simpson-Roberts dilatation catheter that was then being used by his assignee and he did not know how to make a balloon small enough to [\*11] be attached to such a catheter and pass through said lumen (JPR 170, 172, 192, 221, 222, 226, 240, 247). He did not have a complete conception of the invention prior to the time that Williams and Mar became involved in the project. Williams and Mar were instrumental in developing the technology which made it possible to construct a catheter and balloon combination having dimensions sufficiently small to serve as the second dilatation catheter and balloon set forth in counts 1 and 2 (JPR 350-351, 364-365, 391-407, 98-119, 36, 45-47, 49-50) and thereby transform Samson's idea into a complete conception of the invention. This fact was apparently recognized when the Samson et al application was filed naming Williams and Mar as joint inventors. Since Mar did not become involved with the project until late November 1984, only activities which occurred after that time may be relied upon by Samson et al to establish joint conception and reduction to practice on their behalf. *Perkins v. Engs*, 118 F.2d 924, 49 USPQ 247, 251 (CCPA 1941); *Willis v. Suppa v. Koehler*, 209 USPQ 406, 410 (Bd.Pat.Int. 1980).

Mar purportedly did some bench testing of prototypes meeting the terms of count [\*12] 1 between January and April 1985. However, the only noninventor who is alleged to have witnessed any of the tests is one Dave Morrison, who did not testify (JPR 107-108). The only evidence independent of the inventors with respect to activities by Samson et al after November 1984, when Mar started working on the project, is the testimony of Dr. Stack of Duke University. A declaration by Stack was submitted as part of the Samson et al case-in-chief (JPR 1-6). Stack was also called as a deposition witness during the junior party's case-in-rebuttal (JPR 620-755). In fact he was the only witness to testify during the Samson et al rebuttal testimony period. The purpose of a rebuttal testimony period is supposed to be to permit a party to obtain testimony to rebut the opponent's case-in-chief. III Rivise and Caesar, *Interference Law and Practice*, Section 381 (Michie Co. 1947). However, Samson et al rely primarily on Stack's rebuttal testimony to bolster their own case-in-chief. Crittenden et al have not objected to and, in fact, through cross-examination elicited much of Stack's rebuttal testimony. Accordingly, we do not treat the rebuttal testimony any differently than the [\*13] testimony submitted by Samson et al during their case-in-chief.

Between March 25, 1985 and April 4, 1985, Stack received two prototype .018" profile catheters from Williams and tested one of them on a dog on April 4, 1985 (JPR 1-6). The catheter was not tested on a human prior to the July 30, 1985 filing date of the Samson et al application or even up to the time of Stack's deposition in March 1988 (JPR

694-699). Stack inserted the .018" catheter into the dog's distal circumflex artery and inflated and deflated it a few times and moved the .018" catheter back and forth with respect to a larger dilatation catheter (JPR 5) during the April 4, 1985 test, but he did not and could not use it for its intended purpose of dilating a stenosis in the vessel since the vessel did not contain a stenosis (JPR 642). Thus, the steps of count 2 were not carried out with the dog model and the device of count 1 was not tested under actual use conditions or under conditions that would simulate actual use conditions as required for an actual reduction to practice. *Newkirk v. Lulejian*, 825 F.2d 1581, 3 USPQ2d 1793, 1794 (Fed. Cir. 1987). Stack's opinion to the effect that device would work, as [\*14] intended, if used on humans cannot take the place of evidence in the record (JPR 668). *Paine v. Inoue*, 195 USPQ 598 (Bd.Pat.Int. 1976). Moreover, Drs. Faxon and Spears who, like Stack, have had considerable experience in the field of angioplasty, which involves dilatation of arterial stenoses with a balloon catheter, both testified to the effect that dogs do not develop stenoses in their vessels and that one could not determine whether the invention in issue would work successfully in humans based on the test performed by Stack on a dog (SPR 198, 252). Faxon points out that a critical part of being able to dilate a lesion is getting the balloon through the stenosis (SPR 210). In the case of the dog vessel, this problem does not arise since the vessel has no stenosis. Coinventors Mar and Samson were also of the view that human clinical tests were required to show that the invention would work for its intended purpose (JPR 127-128, 175-176). After carefully considering all of the evidence of record, we hold that Samson et al have failed to establish that they reduced the invention to practice prior to the filing date of the senior party. Samson et al did not raise the question [\*15] of conception plus diligence in their brief (main brief, page 1) and thus we need not determine whether the senior party conceived the invention in late March or early April 1984 as alleged in the senior party's brief. Accordingly, Crittenden et al are entitled to prevail on the question of priority.

### III

#### SAMSON ET AL - BEST MODE

Crittenden et al contend that the evidence submitted by Samson et al in support of their case for priority shows that they concealed the best mode known to them for practicing the invention when they filed their application. Crittenden et al point out that the Samson et al disclosure merely states on pages 5 and 6 that the part 41 comprising the balloon 43 for the second dilatation catheter "consists of a plastic tube of a suitable type such as polyethylene of a length ranging from 20 to 30 centimeters." On pages 12 and 13 of their brief, Crittenden et al refer to testimony by Mar and Frisbie to the effect that a special size tubing (JPR 116-119) is needed and that it must be irradiated (JPR 33-36, 145) in a process that was developed in-house by ACS in order to properly control the diameter to which the tubing can be blown into a balloon (JPR 33-34, [\*16] 547-548, 557-562, 614, JPX 4, pages 00551 and 00590). They also note Samson testified that it was a policy of ACS to keep processes secret when filing a patent application (JPR 221-225) and that Williams requested that information concerning curing the adhesive 47 (Fig. 4) with ultraviolet light and information regarding heat treating the wire 49 (Fig. 4) be removed from the application prior to filing (JPR 366-367, 397-407). After reviewing the cited evidence, it is clear to us that Samson et al concealed their best mode with respect to all three of the above cited items, i.e., radiation of the tubing used for the balloon 43, heat treating the guide wire 49 and curing the adhesive 47. Accordingly, we hold that claims 1 to 26 of the Samson et al application corresponding to the counts in issue are unpatentable to Samson et al under 35 USC 112, first paragraph. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 USPQ2d 1737, 1745 (Fed. Cir. 1987); *Dana Corp. v. IPC Limited Partnership*, 860 F.2d 415, 8 USPQ2d 1692, 1695 (Fed. Cir. 1988).

### IV

#### SENIOR PARTY'S POST HEARING MOTION

The senior party has filed a post hearing motion (Paper No. 81) to add U.S. Patent No. [\*17] 4,793,350 assigned to ACS and a corresponding European patent application to their record. The additional evidence is said to further show that the junior party did not reduce to practice the invention in issue prior to their July 30, 1985 filing date. The motion could be dismissed as moot in view of the fact that we have held that Samson et al have failed to prove their alleged

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actual reduction to practice. However, we agree with Samson et al that the motion should be denied for the reasons stated in the opposition (Paper No. 82).

The motion is denied.

V

#### JUDGMENT

Judgment as to the subject matter in counts 1 and 2, all of the counts in issue, is hereby awarded to Crittenden et al, the senior party. Based on the record before us, James F. Crittenden and James J. Frassica are entitled to a patent containing claims 1 to 26, 48 and 49 corresponding to the counts in issue. Wilfred J. Samson, Ronald G. Williams and Craig E. Mar, the junior party, are not entitled to a patent containing claims 1 to 26 corresponding to the counts in issue.

#### **Legal Topics:**

For related research and practice materials, see the following legal topics:

Patent LawDate of Invention & PriorityReduction to PracticePatent LawInequitable ConductGeneral OverviewPatent LawU.S. Patent & Trademark Office ProceedingsGeneral Overview

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